UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RONALD MORROW, Derivatively on Behalf of Nominal Defendant NEWLINK GENETICS CORPORATION, Plaintiff, v. CHARLES J. LINK, JR., THOMAS A. RAFFIN, PAUL R. EDICK, PAOLO PUCCI, JOSEPH SALURI, ERNEST J. TALARICO, III, NICHOLAS VAHANIAN and LOTA S. ZOTH, Defendants, and NEWLINK GENETICS CORPORATION, Nominal Defendant.	Case No: **VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff Ronald Morrow ("Plaintiff"), by and through his undersigned attorneys, brings this shareholder derivative action for the benefit of nominal defendant, NewLink Genetics Corporation ("NewLink" or the "Company"), against certain current and former officers and members of the Company's board of directors (the "Board") seeking to remedy defendants' violations of §14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiff makes these allegations upon personal knowledge as to those allegations concerning Plaintiff and, as to all other matters, upon the investigation of counsel, which includes without limitation: (a) review and analysis of public filings made by NewLink and other related parties and non-parties with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and other publications disseminated by certain of the defendants (as defined below) and other related non-parties; (c) review of news articles, shareholder communications, and postings on NewLink's website concerning the Company's public statements; (d) review of the pleadings

and other documents in the securities class action lawsuit captioned *Nguyen et al. v. NewLink Genetics Corporation, et al.*, File No. 1L16-cv-3545-WHP (S.D.N.Y.) (the "Securities Class Action"); and (e) review of other publicly available information concerning NewLink and the defendants.

NATURE OF THE ACTION

1. This is a shareholder derivative action on behalf of nominal defendant NewLink seeking to recover damages caused by defendants' violations of the federal securities laws and to pursue remedies under § 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder against the Board as a result of defendants causing the Company to issue materially misleading statements and/or omitting material information in the Company's 2016 Proxy statement regarding compensation, as well as claims for breach of fiduciary duty in connection with the Company's algenpantucel-L drug trials from September 17, 2013 until the present (the "Relevant Period").[1]

2. NewLink is a biopharmaceutical company that has spent years attempting to discover, develop, and commercialize immunotherapeutic products to enhance treatment options for patients with cancer. However, the Company has yet to be able to commercialize any of its products or produce any income for its efforts.

3. Though unsuccessful in ever bringing any product to market, the Company has been quite successful in raising expectations of and money from, the investing public, reaching a market cap of over one billion dollars, as described herein.

4. The Company's former lead product candidate, algenpantucel-L (or HyperAcute Pancreas), an investigational immunotherapy, was – during the period between May 2010 and May

[1] The false and misleading statements were issued in the Company's public filings from approximately September 17, 2013 to May 9, 2016; however, the wrongs complained of herein continue through to the present as NewLink's internal controls remain deficient.

2016 – being studied in Phase III clinical trials for patients with pancreatic cancer.

5. Throughout the Relevant Period, defendants caused the Company to issue materially misleading statements and/or omit material information concerning the commercial prospects, efficacy, and clinical trial protocols of algenpantucel-L.

6. Algenpantucel-L was a drug candidate of interest to investors since pancreatic cancer causes approximately 7% of all cancer deaths in the United States, and there is virtually no significantly successful treatment for the disease. As a result of pancreatic cancer's qualification as a rare medical condition, the United States Food and Drug Administration (the "FDA") granted algenpantucel-L an "Orphan Drug" designation. This meant that there would be an opportunity for exclusive marketing rights, clinical tax research incentives, and exemption from filing fees, which was also attractive to potential investors.

7. In order to receive necessary approval from the FDA, drugs and other medical treatments must first pass a series of clinical trials, with a "Phase 1" trial of a small group of volunteers taking the proposed drug to test the safety of the medication; "Phase 2" trial of up to several hundred volunteers to test the drug for side effects, safety and efficacy; and "Phase 3" trial of a minimum of three hundred volunteers for a much longer period of time than Phase 2, to test for efficacy. If the drug passes the Phase 3 trial it goes onto the final pre-marketing clinical trial, the "Phase 4" trial, in which an even larger population is tested.

8. NewLink started a Phase 2 trial of algenpantucel-L and completed enrollment of only 70 volunteers in February 2010. The Phase 2 trial had no control group, typically considered to be an essential component of a clinical study. Because the Phase 2 trial had no control group and was limited to 70 participants, the Phase 2 trial was very limited in its ability to produce scientifically statistically meaningful indicia of efficacy of the drug (though the Phase 2 trial

could produce statistically meaningful indicia of safety and side effects of algenpantucel-L).

9. In May 2010, just three months after beginning the Phase 2 trial, the Company initiated a Phase 3 trial on algenpantucel-L, which the Company titled the "IMPRESS" (IMmunotherapy for Pancreatic REsectable cancer Survival Study) study, with the goal of testing the overall survival/length of survival rate of patients utilizing the algenpantucel-L therapy as opposed to those engaged in standard pancreatic cancer therapy.

10. Throughout the Relevant Period, defendants repeatedly represented to investors that the Company's Phase 3 trial – the IMPRESS sturdy – was initiated "based on encouraging Phase 2 data that suggests potential to improve both disease-free and overall survival."

11. Despite Defendants' public representations, the Phase 2 trial conducted prior to Phase 3 was limited in size to only 70 patients, contained no control group, and therefore did not produce statistically meaningful data from which scientifically valid conclusions concerning the drug's efficacy could be drawn.

12. Utilizing false and misleading statements concerning the Phase 2 trial results, and their initiation of the Phase 3 IMPRESS study, defendants caused NewLink's stock price to be artificially inflated, thereby allowing certain of the defendants to reap millions of dollars through suspiciously timed sales of huge portions of their NewLink stock holdings, as detailed herein.

13. Throughout the Relevant Period, defendants continued to make materially false and misleading statements and/or material omissions regarding the prospects of algenpantucel-L and the results of the Phase 2 trial, the stringency of the IMPRESS Phase 3 clinical trial design; the trial results regarding overall survival endpoint with and without algenpantucel-L; and the Company's likelihood of achieving positive results in its clinical trials, all the while failing to disclose the regulatory clinical practice violations committed by those working on the IMPRESS

study.

14. For example, on September 17, 2013, defendants caused the Company to issue a press release entitled NewLink Genetics Completes Patient Enrollment in Phase 3 Algenpantucel-L (IMPRESS) Clinical Study." In the press release, defendant Charles Link, Jr. ("Link"), the Company's Chief Executive Officer ("CEO") and Chairman of the Board, stated, in pertinent part:

> …We are confident in the stringency of this study design and the statistical power provided by the large number of patients participating in this trial as we enthusiastically look forward to the clinical results.

15. Further, on March 11, 2014, in a conference call with analysts and investors, defendant Link stated, in pertinent part, "[w]e are encouraged by the apparent lengthening of survival in the combined arms of this study…" This statement was false because neither the Phase 2 nor Phase 3 trials ever produced results indicating that algenpantucel-L lengthened the lives of pancreatic cancer patients.

16. As a result of defendants' misconduct, the Company's stock became artificially inflated, rising from $17.07 per share on September 17, 2013, the start of the Relevant Period, to a high of $58.73 per share on April 9, 2015, an increase of more than 344% over a year and a half.

17. In reality, unbeknownst to investors, these statements and omissions were materially false and misleading. For instance, with regard to the stringency of the IMPRESS study design, the Company included patients who did not have the appropriate qualifications to be in the trial at all. Including these unqualified patients allowed certain of the defendants to receive substantial performance bonuses tied to meeting IMPRESS study enrollment targets.

18. Defendants also misrepresented the total survival duration of patients using standard therapy (the control group) to falsely indicate shorter survival spans, so as to falsely claim that patients in the IMPRESS study, who were taking algenpantucel-L, experienced a prolonged

life. However, the group of patients taking algenpantucel-L were in fact doing worse than those in the control group undergoing standard therapy.

19. Throughout the Relevant Period, as the false and misleading statements and material omissions resulted in the Company's stock price more than tripling, defendant Link sold approximately 72% of his shares of NewLink stock; defendant Vahanian sold approximately 83% of his shares of NewLink stock; defendant Talarico sold approximately 63.47% of his shares of NewLink stock; defendant Saluri sold approximately 37.8% of his shares of NewLink stock; and defendant Raffin sold approximately 24.8% of his shares of NewLink stock.

20. In the weeks prior to the Company's announcement on May 9, 2016 concerning the Second Interim Results (described below) of the IMPRESS study (the results were so poor that their announcement resulted in a 30% drop in the Company's stock price), while the Company's stock was still trading near its artificially inflated all-time high due to the false and misleading statements detailed herein, defendants Link, Vahanian, Talarico, and Raffin sold significant quantities of their NewLink stock. Defendant Link sold 40,000 shares for nearly $2 million in proceeds; defendant Vahanian sold 95,000 shares for $4.7 million in proceeds; defendant Talarico sold 20,532 shares for over $1 million in proceeds; and defendant Raffin sold 20,694 shares for over $1 million in proceeds.

21. The truth concerning the IMPRESS study began to emerge on May 9, 2016, when the Company announced algenpantucel-L did not meet the goals set for the Phase 3 trial. The results revealed that patients receiving algenpantucel-L survived for an average of 27.3 months in the IMPRESS study while those treated with standard therapy had a median survival of 30.4 months. In other words, the overall survival rate of the control group patients receiving standard therapy was nearly ***50% longer*** than that represented by defendants, indicating that algenpantucel-